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ABSTRACT

ACCOMMODATION FOR HEAD GROWTH IN PEDIATRIC COCHLEAR IMPLANTATION. David R. Marks, Robert K. Jackler, and Grant J. Bates. Coleman and Epstein Laboratories, Department of Otolaryngology, University of California, San Francisco, CA. (Sponsored by J. Cameron Kirchner, Division of Otolaryngology, Department of Surgery, Yale University, School of Medicine, New Haven, CT).

Accommodation for head growth is one of several challenges unique to pediatric cochlear implantation. It has been estimated that an electrode implanted at the age of two years must be capable of expanding at least 2 to 3 centimeters if it is expected to function until adulthood.

Previous devices with redundant loops of lead wire have elongated effectively only when placed within air containing spaces such as the mastoid or middle ear. However, when the wire traversed soft tissue overlying the parietal bone, it became enmeshed in fibrous tissue and did not elongate.

The present study evaluated 3 different configurations of expansile devices that were enclosed in fluorinated ethylene propylene (Teflon®) sheaths to deter fibrous ingrowth. Twelve such devices were implanted across the calvaria of 4 newly-weaned piglets. Skull growth and changes in electrode dimensions were documented by sequential computed tomographic scans. At three months of age the cranial circumferences had increased substantially. The animals were then sacrificed and the devices examined histologically.

In all experimental animals satisfactory expansion of the redundant lead wires took place with no incursion of fibrous connective tissue into the

sheath in the majority of cases. This indicates that enclosure of excess lead wire within a teflon envelope may be an effective means of inhibiting fibrous ingrowth. It is hoped that this strategy will prove useful in the cochlear implantation of young children.

INTRODUCTION

Technological advances in the fields of electronics and neurophysiology have led to the development of the cochlear implant -- a surgically implantable neural prosthesis designed to functionally replace the human ear. The cochlear implant is intended for patients with sensorineural deafness in whom the functioning of the sensory hair cells of the cochlea is impaired. These hair cells normally serve to convert sound waves into electrical signals for transmission to the brain. In patients with sensorineural deafness, the ability to convert sound energy into electrical impulses is lacking.

The fact that many auditory nerve fibers often remain intact in patients with sensorineural deafness makes it possible for a cochlear implant to function.[1] It does this by detecting environmental sound energy and then stimulating the surviving neurons with electrical currents of the proper strength, duration and orientation. The neurons, in turn, fire impulses that are identical to those elicited by acoustically stimulated intact hair cells. Thus, the brain interprets these signals as sound.

Cochlear implants of various designs have been successfully used in post-lingually deafened adults to provide auditory sensation where previously there was none. The different types of devices all have certain features in common: a microphone for picking up the sound stimulus, a microelectronic processor for converting the sound into electrical signals, a transmission system for relaying the signals to the implanted components, and a long electrode that is surgically inserted into the cochlea so that the

electrical impulses are delivered directly to the auditory neurons (Figure 1).[1]

The success achieved with cochlear implantation in adults has stimulated the experimental implantation of these devices in deaf children, in whom the effects of auditory isolation may be especially severe. Sociological studies[2,3,4] of the deaf population in the 1970's have shown that most congenitally deaf individuals are deficient in linguistic skills and may suffer experiential deprivation as well as being deficient both economically and socially. For example, the level of education attained by deaf persons is lower than the level attained by hearing persons, and although the unemployment rate among deaf individuals compares favorably to that of hearing persons, deaf individuals' median incomes are only 72 percent of those for the general population. Such economic differentials are directly related to age at onset of deafness, with congenitally deaf individuals having the lowest average and post-lingually deafened individuals the highest.[3] In addition, a smaller proportion of persons in the deaf population marry than in the general population (67% as many males and 85% as many females), and they marry at more advanced ages. Data on childbearing reveals that the number of children born to deaf women is significantly less than the number born to hearing women.[3] These social and economic differences between deaf and hearing individuals, and between prelingually and post-lingually deafened individuals, have been well studied and have been attributed to the better linguistic ability of the more "successful" group.[5] It would seem logical, then, that any effort to achieve cochlear implantation in young children be directed toward improving the child's acquisition of speech and language capabilities.

Figure 1

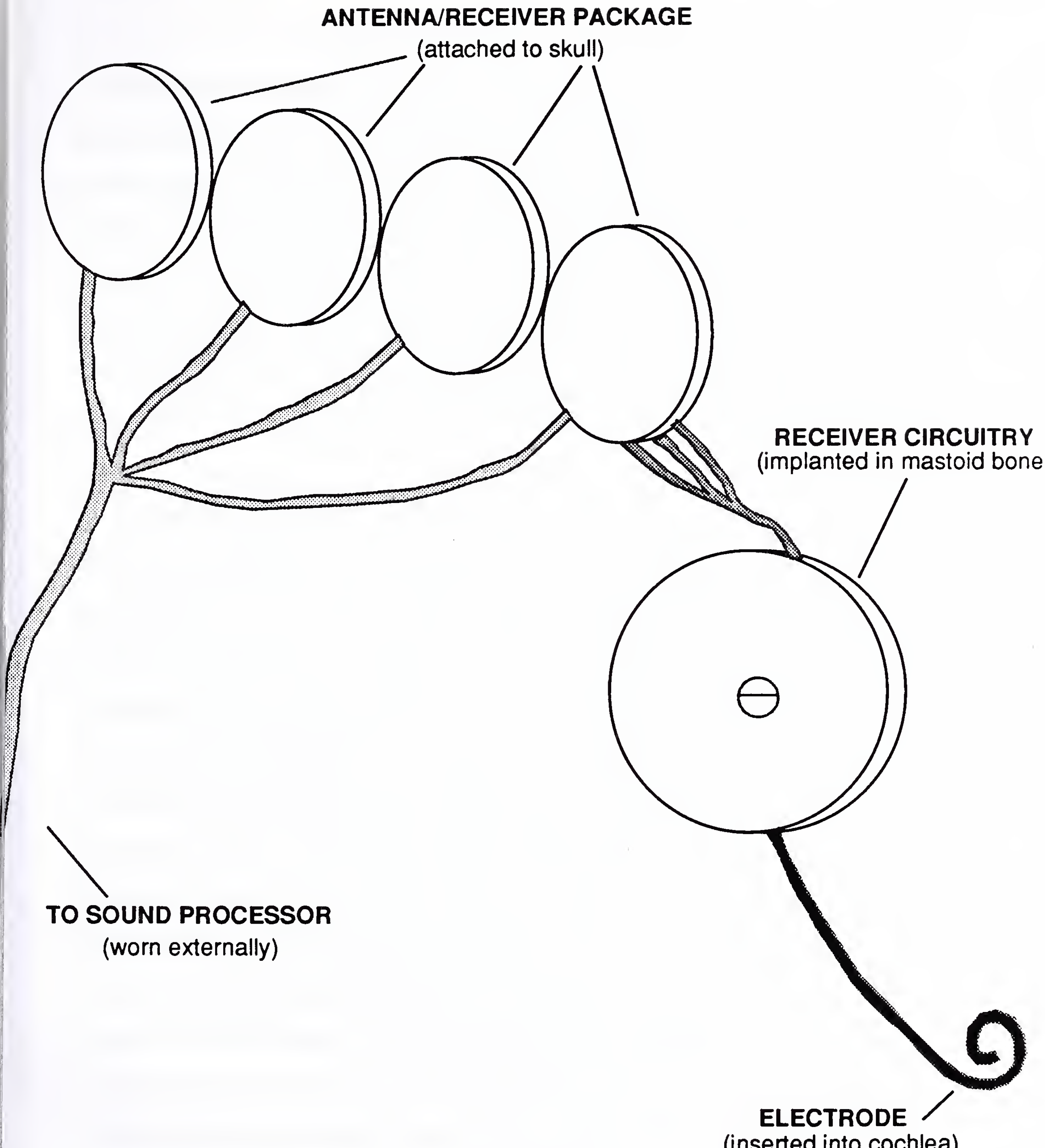

Figure 1: Schematic drawing of the main components of a multichannel cochlear implant device developed at the University of California, San Francisco.

Numerous studies[6,7,8,9,10] using both human and animal models have attempted to elucidate the anatomical and electrophysiological basis of the development of auditory function. The human labyrinth is anatomically mature at approximately the fifth or sixth month of fetal life and the cells which make up the Organ of Corti, the auditory receptor cells, are laid down even earlier in fetal life, between the eleventh and sixteenth weeks of fetal development.[11] Any loss of these specialized receptor cells throughout the life of the organism will result in some degree of hearing loss.

While the *peripheral* auditory structures are firmly established during gestation, a number of investigators[12,13,14,15] have demonstrated in animals that neurons of the *central* auditory pathways achieve adult morphology postpartum and that the developing central auditory nervous system in these animals is capable of some degree of anatomical plasticity. Levi-Montalcini[13] and Parks[14] investigated the effect of experiential influences on brain development by removing the embryonic otocyst of the developing chick unilaterally and allowing the embryo to continue to develop. Their data show that embryonic deafferentation has significant effects upon the subsequent development of the avian cochlear nuclei. They found that otocyst ablation caused changes in the migration of auditory central nervous system structures and regression in the size and growth of these structures on the ipsilateral side of the lesions. From these results they concluded that primary cochlear fibers exert significant influence on the growth and maintenance of their target neurons.

Other groups[16,17] have investigated the possibility that degeneration in central auditory nuclei may result from attenuation of auditory stimulation

without disruption of the receptor organ or afferent inputs. Such studies of the effects of auditory deprivation in animals may have important correlates for human auditory development. Webster and Webster[17] designated a group of mice to be raised by an avocal mother in a sound-attenuated chamber from 3 to 45 days of age, and then moved the group to the regular animal colony for the next 45 days. A control group was raised from birth until 90 days in the regular animal colony. The animals were sacrificed and the ears and brains studied at day 90. A third group was raised in auditory deprivation for 45 days and was sacrificed at the end of that period of time for study. Their data show that the mice raised in partial auditory deprivation for 45 days and then in a normal environment had smaller neurons than 90-day normals and the same size neurons as 45-day deprived mice. Although the effects on the hearing of each group was not measured, the data indicate that there is a critical period, before the age of 45 days in mice, during which auditory stimulation may have an effect on the maturation of the auditory CNS.

Silverman and Clopton[18] studied the electrophysiological effects of the attenuation of auditory stimulation. They investigated binaural interaction in rats that had been partially deprived of sound during development by ligation of the external auditory meatus at 10 days after birth. The recording of unit activity in the inferior colliculus was carried out after 3-5 months of deprivation. Their findings suggest that the relative efficacy of ipsilateral and contralateral projections to the inferior colliculus of the rat is mediated by acoustic activation and is established on a competitive basis.

Studies of the developing visual system show that cortical neuronal activity[19,20,21,22] as well as behavioral activity[23,24] can be permanently

changed based on the visual pattern stimuli experienced during the critical period for development of the visual system. Similarly, in the auditory system, the pattern of sound stimulation experienced by young rats during the first four months of life has been shown to influence the pattern of response at the collicular level. Clopton and Silverman[25] demonstrated that the firing rate of single units in the inferior colliculus increased selectively when stimulated with a familiar sound pattern compared to their firing rate with a novel sound pattern. This suggests that early auditory experience may have an effect on the future ability of the rat auditory CNS to respond to patterned sound stimulation.

Very little data is available regarding critical periods in human sensory development, but a parallel to these investigations is the impaired vision of the surgically corrected congenital cataract patients studied by Senden.[26] For at least 2 weeks, such patients could discriminate forms such as squares and triangles only by counting their corners. This indicates that human visual development may also be influenced by early sensory experience. Although at present there have been no such studies involving the human auditory system, the evidence from animal experiments cited in the preceding paragraphs suggests that it may function similarly.

Thus, there may be a critical period during which auditory stimulation is required for the normal development of the human auditory central nervous system. Lack of auditory stimulation during this critical period may impair speech and language acquisition. Later attempts at cochlear electrical stimulation may be fruitless if their has been reorganization of receptive fields or degeneration of cortical representation in the auditory cortex due to deafferentation.[27] Bateson[28] has likened this concept of a

critical period to the brief opening of a window, with experience influencing development only while the window is open.

Because the critical period for auditory stimulation in humans is probably within the first few years of life, efforts must be directed toward achieving safe implantation as early as possible.[29] Although the optimal timing for implantation of a congenitally deaf child has yet to be determined, most investigators are striving to develop implant systems appropriate for use in the 18 to 24 month old child. Prior to the age of18 months, practical surgical and social factors will probably mitigate against implantation at such an early age. The most important of these factors are probably the delay in diagnosis of severe neonatal deafness[30] and the difficulty of placement of the prosthetic device on the relatively thin and friable infant calvarium.[31] In addition, early intervention and treatment are often hampered because the parents are unable to resolve their shock and grief at learning of their child's hearing handicap.[32]

Experience with intracochlear prostheses in the pediatric population has thus far predominantly involved the implantation of single channel devices in older children and adolescents.[33] These systems are designed to stimulate large portions of the cochlear neuronal population simultaneously, while more sophisticated multichannel cochlear implants filter acoustic stimuli into different frequency ranges and stimulate discrete segments of the auditory nerve with the frequency range that is appropriate for that membrane segment.[1] There is a concern that if the auditory cortex of a child becomes "locked-in" to the stimulation pattern of a single channel or even a multichannel cochlear electrode the central nervous system may lose its inherent plasticity and he may not be able to benefit

from the greater range of auditory stimulation anticipated from future advances in cochlear implant technology.[34]

Although the concerns noted above have not been completely addressed, the benefits of early cochlear implantation may outweigh the risks by providing auditory thresholds that enable the deaf child to detect speech and environmental sounds.[35] Lousteau[36] has shown that early electrical stimulation via cochlear implantation in perinatally deafened newborn guinea pigs may retard degeneration of inner hair cells and may also preserve spiral ganglion cells. He found a significantly larger number of spiral ganglion cells remained in stimulated ears 6 weeks after deafening than were seen in the unstimulated ears of the same animals. Similarly, Wong-Riley *et al* [37] have shown that neuronal activity in the auditory nuclei of the brain stem can be maintained by intracochlear electrical stimulation of unilaterally deafened animals, producing a deafened ear that has a near-normal ganglion cell population. If these trophic effects also occur in humans it would suggest that early implantation after perinatal deafness may affect the success obtainable with electronic hearing prostheses, since the efficacy of the cochlear implant is dependent on the survival of spiral ganglion neurons.[1]

One out of every 1,000 children is born deaf, and another out of each 1,000 becomes deaf in early years due to meningitis or other serious illnesses.[32] Since very few of these children have other physical deformities, the hearing impairment may go undetected for quite some time.[30] In 75% of cases, the parents first suspect hearing loss, while the physician detects it initially in only 7% of cases.[38] Children can be tested audiologically a few days after birth using both informal testing, consisting of behavioral observations of a child's response to sound stimulation, and

more formal testing which includes visual reinforcement audiometry (VRA) and condition play audiometry (CPA). When more objective measures of hearing acuity are required, auditory brainstem response audiometry (ABR), also known as brainstem electrical response audiometry (BSER) is utilized. The latter is an electrophysiological technique that measures electrical brain stem activity in response to auditory stimuli.[32] These techniques are able to give definitive data about the hearing status of children at a very early age.

Once the diagnosis of severe bilateral deafness is made in the young child, the decision must be made whether to use a cochlear implant as the primary therapeutic modality. However, before the newer generations of sophisticated multichannel cochlear implant devices can be accepted for widespread use in the pediatric age group, special consideration must be given to the unique difficulties that can be anticipated in children.[39] Among these is the problem of head growth. Although the cochlea is adult size at birth, the temporal and parietal bones continue to grow into adulthood.[40] Since the antenna/receiver package of the cochlear implant device (figure 1) is firmly fixed to the cranium, this skull growth could cause tension to develop along the axis of the lead wire, resulting in the potential extraction of the active portion of the electrode from the cochlea. As the shorter single channel devices are designed to stimulate large portions of the cochlear neuronal population simultaneously, small movements of the electrode within the scala tympani may not be significant, as long as the active portion remains in the cochlea. Since the longer multichannel devices are designed to stimulate discrete segments of the auditory nerve, they may be more prone to functional derangement due

to small changes in electrode position. Because of their length, however, they are less apt to become completely extracted from the cochlea.

Two recent studies[40,41] have revealed that over 50% of postnatal temporal bone growth occurs during the first two years of life and continues at a more gradual pace until the late teenage years. In addition, they revealed that a second phase of growth of a lesser magnitude occurs during adolescence. The implications are that a cochlear implant placed at the age of two years must be capable of accommodating at least two to three centimeters of growth if it is to remain in place until adulthood. One possible solution to this problem would be to periodically explant the ear and reinsert a larger device. However, this would subject a growing child to numerous surgical procedures, and the repeated explantations and reimplantations may cause damage to the cochlea and surviving auditory neurons. Clearly, the preferable strategy is to utilize an expandable device.

Orthopedic surgeons who work with children have also had to devise effective strategies to overcome growth. This problem has been especially acute in children with the congenital defect osteogenesis imperfecta (OI), in whom abnormal development of the long bones occurs leading to curvature, bowing, and multiple fractures. Early treatment of this disease consisted of multiple osteotomy and internal fixation with a fixed intramedullary rod.[42,43] However, the non-extensible rods were outgrown by the bone with the development of angulation or fracture in the unsupported bone distal to the tip of the rod, and in some cases resulted in the rod penetrating the cortex.[44] It was found that non-extensible rods in children needed to be revised every two to two and a half years,[45,46,47] with some children requiring a revision operation almost every six months.[48] To overcome this problem, Bailey and Dubow[49] introduced an extensible

rod consisting of a hollow sleeve with an internal, telescoping obturator pin. Many studies[43,48,50] have subsequently shown that, by accommodating the growth of the long bones of children with OI, the extensible Bailey-Dubow rod effectively increases the average length of time between replacement operations and yields lower removal rates.

While a telescoping apparatus is not a practical solution for cochlear implantation due to the size of device, it seems essential that some form of redundancy of implant lead wire be incorporated into any prosthesis designed to accommodate for head growth. A linear segment of electrode will slide through dense fibrosis because its Silastic coating will not chemically bond to the surrounding tissue. By contrast, O'Donoghue, *et al* [51] have shown that when the central portion of a redundant geometric pattern such as a loop, helix, or sinusoid becomes embedded in fibrous connective tissue it is unable to expand. One strategy to maintain expansibility of a redundant electrode when it traverses soft tissue would be to enclose it in a protective sheath which excludes fibrous tissue. This strategy has been demonstrated useful in permitting the elongation of cardiac pacemaker lead wires in an animal model,[52] but such a solution has not yet been demonstrated in the temporal bone.

An alternate strategy is to place an expansile segment in an air-containing space such as the middle ear or mastoid where fibrous ingrowth is less likely.[51] This is the approach taken by House and his colleagues[53] during surgical implantation of the House 3M single channel cochlear implant device. An excess loop of lead wire is placed within the mastoid cavity. However, fibrous tethering of the electrode where redundant loops contact the walls of these confined spaces seems probable, and as noted above, small movements of a single channel device may not have as much

functional consequence as a small movement of a multichannel device along the scala tympani. A similar strategy is also used in the placement of ventriculo-peritoneal (VP) shunts in children with hydrocephalus.[54,55] A variable length (up to 50 cm) of shunt tubing is coiled-up and placed free in the peritoneal cavity with the hope that it will play-out during truncal growth. However, Brian,*et al* [56] have shown in their series that approximately 4% of these children will require revision surgery due to displacement of the shunt tip from the ventricle secondary to growth of the child despite redundant catheter lead in the peritoneal cavity. This statistic most likely underestimates the problem since many of the children require a revision procedure, due to occlusion of the catheter tip or other mechanical problems, before the effect of growth on shunt placement can manifest itself.[57]

The primary goals of the present study were to evaluate techniques intended to exclude fibrous ingrowth from expansile wire segments and to optimize the geometric configuration of an electrode designed to accommodate for head growth in pediatric cochlear implantation.

MATERIALS AND METHODS

The animals used in the study were 4 newly-weaned, one-month old farm pigs. Swine were chosen because of their rapid growth rate and large increase in size. Over the course of the study (3 months) the animals grew from approximately 15 to over 50 Kg in weight. A total of 11 expansile devices were implanted. In three of the animals, three devices were laid in parallel across the calvarium while in one animal only two devices were placed on the calvarium. Each expansile device consisted of a bundle of four platinum-iridium wires covered by a 1 mm-thick coating of Silastic® (silicon rubber), similar to the lead wire used in human cochlear implants. The expansile portion of each electrode was enveloped by a sheath of 50 micron-thick Teflon® (FEP - fluorinated ethylene propylene) which was heat sealed on all sides except for two small openings to allow the exit of each end of the electrode. Three different configurations were evaluated for their ability to accommodate for head growth. They were selected because of the relatively two-dimensional planar configuration of the lead wires which would take up a minimal amount of space within the sheath and decrease the size of the entire device (Figure 2):

A. A single loop of electrode lead wire (Approx 1.5 cm in length) was enclosed in a square envelope of Teflon® (1.5 x 1.3 cm). The ends of the electrode exited the bag on opposite sides and were welded to flat pieces of stainless steel containing holes through which screws could be inserted (N=6).

Figure 2

EXPERIMENTAL CABLE EXTENSION DEVICES

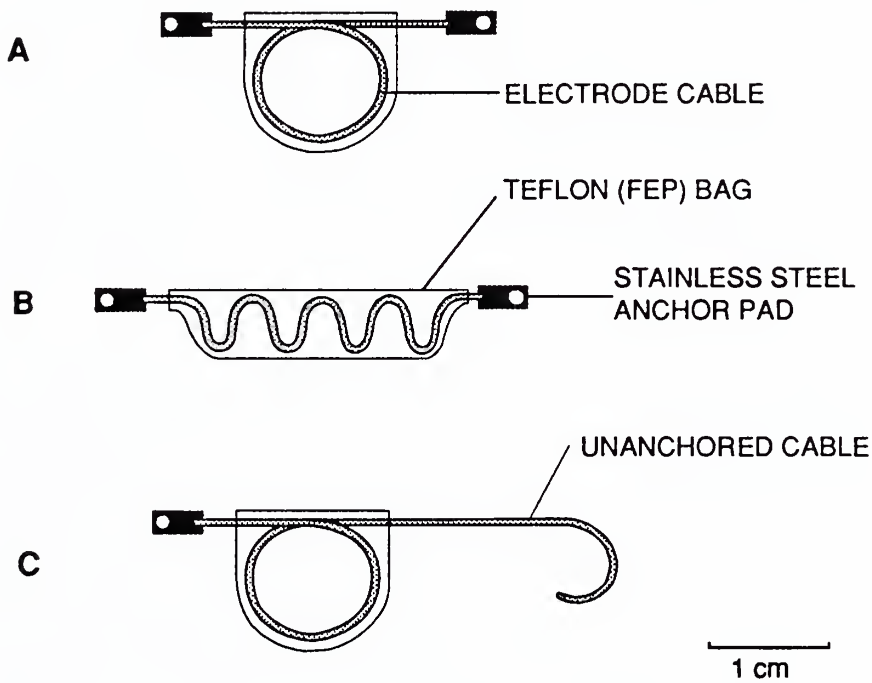

Figure 2: Expansile devices employed in this study: a) Simple loop anchored at both ends, b) Flat sinusoid anchored at both ends, c) Simple loop anchored at one end only.

B. A sinusoidal pattern of electrode lead wire (Approx 5.0 cm in length) enclosed in a long rectangular Teflon® sheath (3.5 x 0.5 cm). The ends of the electrode exited the sheath on opposite sides and were welded to stainless steel as above (N=4).

C. A single loop of electrode lead wire (Approx 1.5 cm in length) enclosed in a square bag of Teflon® (1.5 x 1.3 cm). Only one end of the electrode was welded to stainless steel and screwed into the skull. The other end was molded into a curve (2.5 cm) similar to that of the intracochlear portion of a cochlear implant device. There was no attachment by which it could be fastened to the skull (N=1).

Anesthetic induction was achieved with an intramuscular injection of ketamine (20 mg/kg) and xylazine (2 mg/kg). During surgery, anesthesia was maintained with 2% halothane by snout-mask. Using aseptic technique, skin on the dorsal surface of the head was opened with a #15 blade, the underlying connective tissue and aponeurosis were incised, and the calvarium exposed. Periosteal flaps were then reflected from the cranial surface. The expansile devices were laid on the calvarium and holes were drilled into the skull corresponding to the positions of the apertures in the stainless steel connectors. The devices were then screwed onto the cranium using the connector holes. For two of the long sinusoidal devices, before placing them on the calvarium, the outer cortex of the skull was removed with a cutting drill to expose the subjacent medullary space. Cortical bone chips and marrow were collected with a Sheehy bone pate collector (Otomed Inc.). In these two cases the devices were placed in the bony

depressions that had been created and the harvested bone pate was spread as a thin layer over the external surface of the envelope. The type 'B' devices were chosen because they sat in the trough better than the loop devices. This was believed to be due to the flatter configuration of the lead wires. This technique was performed to evaluate the efficacy of the expansile device when placed in a bony channel as compared with placement in subcutaneous fibrous tissue. After the electrodes were screwed into the calvarium, the periosteal flaps were reapproximated over the devices. The subcutaneous tissue and skin were then closed in layers.

Following implantation, skull growth and electrode expansion were measured radiographically. Antero-posterior and lateral radiographs of the porcine skull were obtained for photographic documentation because of the higher quality of the images compared to the computed tomographic scout views. However, the actual measurements were made from the CT scan images because the views were reproducible by maintaining a consistent gantry isocenter for each pig. The spatial resolution of the CT scanner was approximately 2 mm.[58] Immediate postoperative films were compared with those obtained 6 and 12 weeks thereafter.

After the animals had achieved adult size, the original surgical site was reopened and the expansile devices were carefully exposed. The pattern and degree of electrode expansion, as well as any overt disruption or breakage of the devices, was noted by gross inspection. The portion of the calvarium containing the expansile devices was removed *en bloc* and subjected to histological examination to determine the nature of any tissue found inside of the sheaths and to examine the nature of any bony channel formated around the bone pate-covered devices. Fixation was by immersion in a solution of 5% paraformaldehyde and 0.5% gluteraldehyde

in phosphate buffer. Tissue samples were osmicated, dehydrated in serial ethanol solutions, embedded in plastic, sectioned at 2 micron thickness, and stained with toluidine blue.

RESULTS

Growth of Experimental Animals:

The swine tolerated the operative procedure well and there were no cases of sepsis or purulent discharge from the surgical site. One animal expired after an altercation with its brethren shortly following the 6 week measurements. The other three animals continued to grow and thrive until the time of sacrifice, at 4 months of age, at which time they weighed well over 50 kilograms.

Gross Examination of Implanted Devices:

Gross examination of the implanted devices at the time of sacrifice indicated that the Teflon envelopes had maintained their integrity. Fibrous tissue enveloped both the teflon bags and the unsheathed electrode segments but was not adherent to them. The exit points of the electrodes from the bags were of particular interest, as constriction at this juncture may render the device nonexpansile. Although dense fibrous tissue overlay all of these exit sites (Fig 3), expansion did not appear to have been impaired by its presence. The unfastened curved end of the "type C" electrode was bound

down to the skull surface by a particularly large amount of fibrous tissue along its entire exposed length.

All teflon bags, when opened, contained scant amounts of thin serous fluid. Only three of the eight teflon envelopes (37.5%) showed signs of tissue ingrowth on gross examination. In each case the tissue was patchy, at most encompassing one third of the enclosed area. It was thin, rubbery, and friable. This tissue was not always associated with the electrode exit sites, and it occurred, in some cases, in the central regions of the envelope. In all three cases clotted blood was present within the envelope. This suggests that the tissue ingrowth originated from an organizing thrombus.

The bone subjacent to the unsheathed electrode segments was deeply grooved in all cases. In one case the erosion was so deep that the bone grew over the electrode forming a completely closed channel around it. The teflon bags, by contrast, resulted in only shallow depressions in the underlying calvaria.

Histological Examination of Implanted Devices and Associated Tissues:

Histological analysis of the tissue contained within these three bags revealed fresh blood, organizing thrombus, and mature fibrous tissue. This material was both adherent to the enclosed electrodes and lying free within the teflon sheaths. In one of the bags large numbers of diplococci and polymorphonuclear leukocytes were found.

Performance of Expansile Segments During Growth:

All devices effectively elongated and accommodated for the head growth which occurred during the study period. The average electrode expansion, which represents the change in distance between opposite ends of the electrode, was 7.07 mm (Range = 5.7 to 9.0) (Fig 4,5). The average increase in skull diameter was determined from serial, axially oriented computed tomographic scans. The distance between the mandibular rami increased 36 mm in each animal from the time of implantation to the time of sacrifice.

Adequate expansion was achieved with both redundant wire geometric configurations (simple loop, flat sinusoid) regardless of whether there was fibrous tissue within the teflon envelope (Table I). When multiple devices placed across a given animal's head were compared, some variability in their relative growth was noted. This probably resulted from differential growth of the various bone plates traversed by adjacent electrodes. In general, there was greater expansion for the devices that had the largest initial distance between points of attachment. There was also variability in amount of expansion between animals, presumably due to differences in the individual rates of growth.

Formation of a Bony Channel Around an Expansile Device:

When applied to the outer surface of the teflon envelope, bone pate mixed with blood produced a bony layer which encased the devices, thus separating them from the overlying subcutaneous tissue. In the two devices so evaluated, this bony covering consisted of a thin, homogeneous sheet which was examined both radiographically and histologically (Figs 6a,b and 7). The expansion of the two sinusoidal devices placed under bone

compared favorably with those directly exposed to subcutaneous (Table II). Also, in neither of the bone-enclosed devices was fibrous tissue detected within the teflon envelope.

TABLE I

COMPARISON OF EXPANSILE DEVICES

ELECTRODE TYPE	AVERAGE EXPANSION (MM)
SINGLE LOOP SECURED BILATERALLY	5.0 ± 1.73 (N=4)
SINUSOIDAL PATTERN	7.7 ± 2.37 (N=3)
SINGLE LOOP SECURED UNILATERALLY	14.0 ± 0.0 (N=1)

TABLE II

AVERAGE EXPANSION OF SINUSOIDAL PATTERN DEVICES

TYPE	AVERAGE EXPANSION (MM)
BONY CHANNEL	8.0 ± 2.83 (N=2)
NO CHANNEL	7.0 ± 0.0 (N=1)

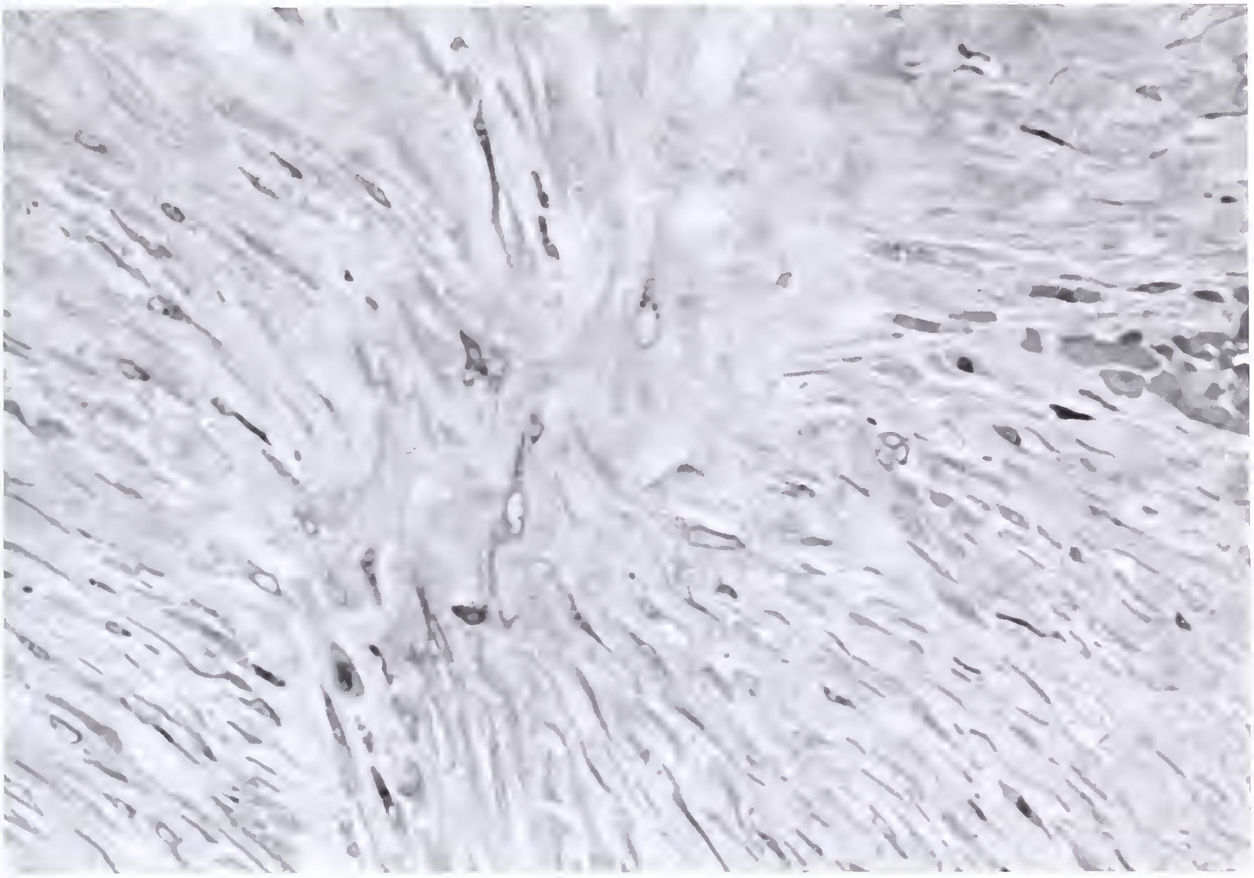

Figure 3: Photomicrograph of tissue taken from the exit point of the teflon envelope (x 800). Note the prominent fibrous component.

Figure 4a: AP plain film taken immediately postoperatively. Compare with figure 4b (next page). Magnification = 2x.

Figure 4b: AP plain film obtained at 12 weeks. The electrode wires and screws are shown at the same scale as in figure 4a (x 2). Skull growth can be noted by the increased distance between the rami of the mandible (M) over time. Electrode expansion is evident by the tightened loops in devices I and III and by the flattened wire in device II.

Figure 5

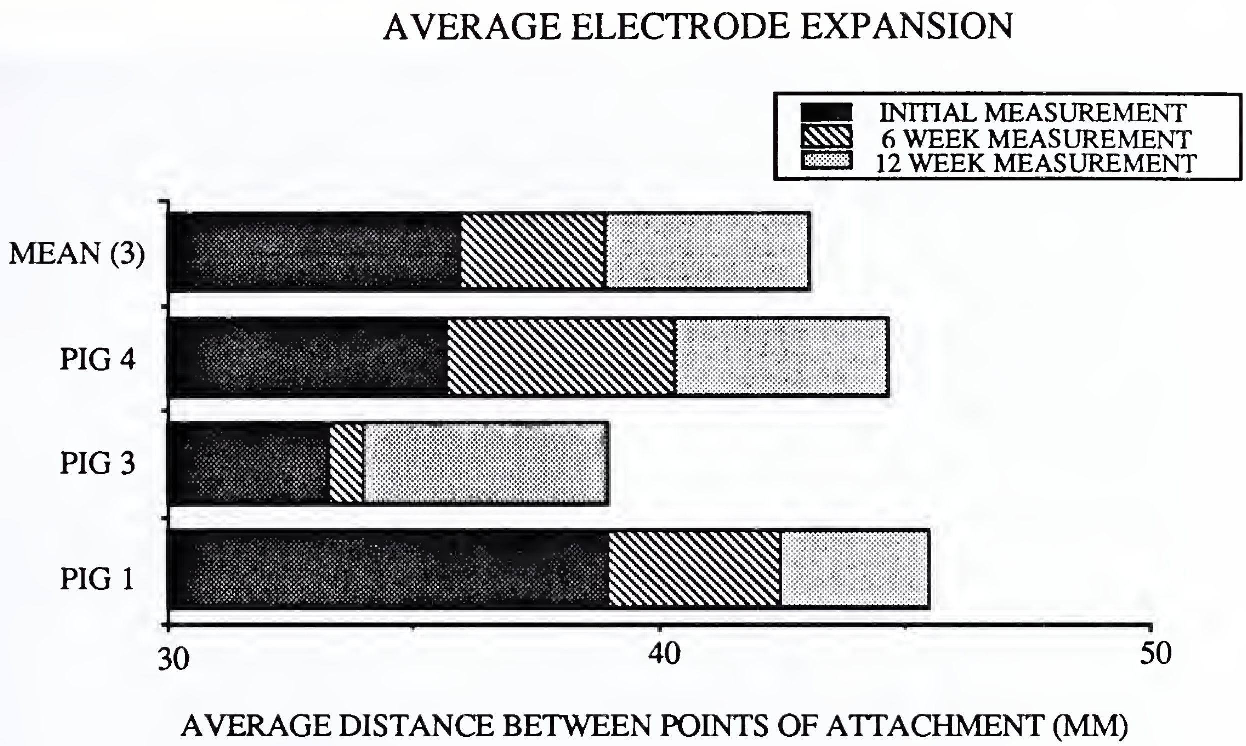

Figure 5: Average Electrode Expansion. Expansion was measured by computed axial tomography as the distance between the fastening screws (N=8). Pig 2 died during the course of the study.

Figure 6a: Early postoperative lateral radiograph in which bone pate (arrows) is seen as a heterogeneous mass of radiopaque material overlying the teflon envelope (Magnification = 2x). Compare with figure 6b (next page).

Figure 6b: At 12 weeks the bone pate (arrows) has formed a smooth sheet overlying the teflon envelope (Magnification = 2x).

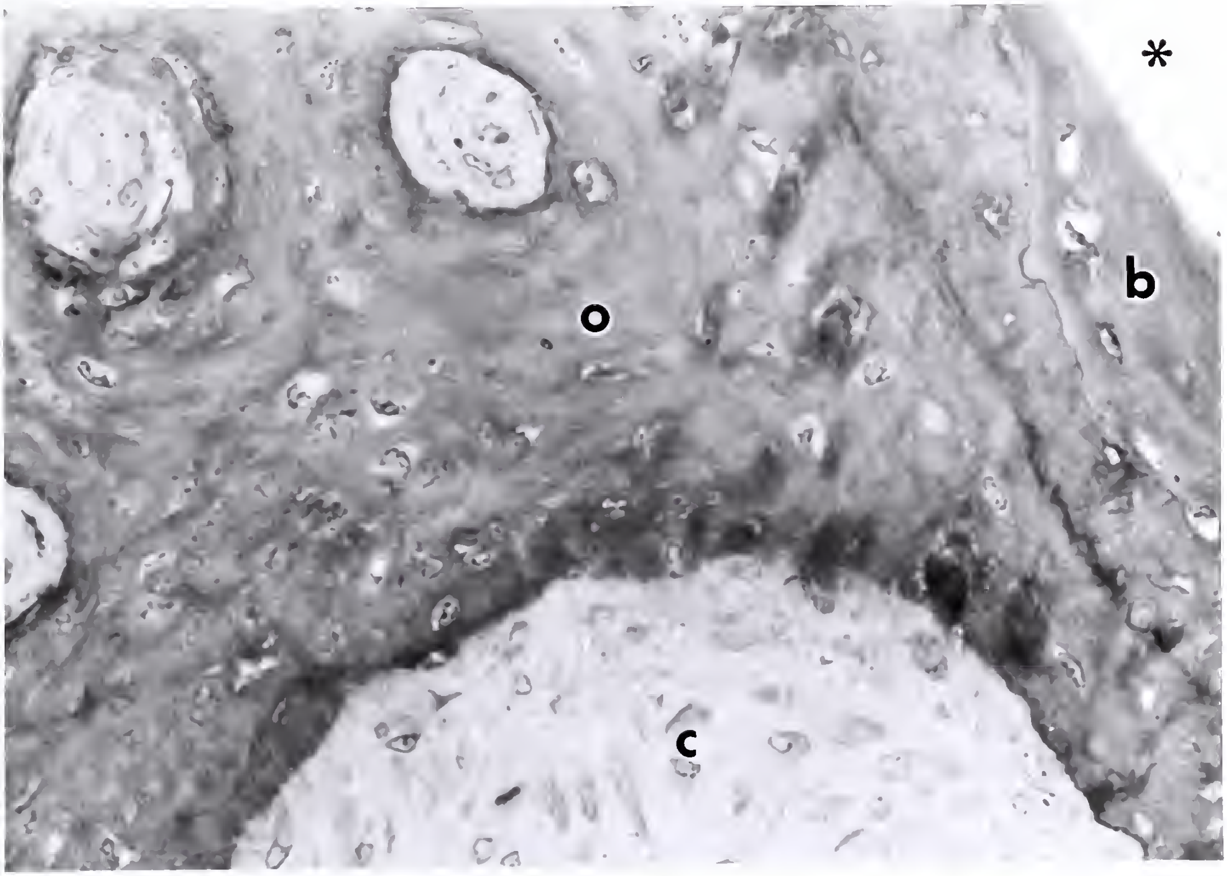

Figure 7: Photomicrograph (x 500) of the bony capsule created over a teflon envelope by use of bone pate mixed with blood. This demonstrates all stages of active bone formation including areas of immature cellular bone (C), osteoid tissue (O), and mature bone (M). (*) = Location of the teflon envelope which was removed for processing.

DISCUSSION

Before the newer generations of sophisticated multichannel cochlear implant devices can be accepted for widespread use in the pediatric age group, special consideration must be given to the peculiar difficulties that can be anticipated in children. The problem of head growth/temporal bone enlargement is one of several of these challenges that are unique to pediatric cochlear implantation and that must be overcome if the prosthesis is to maintain long-term functional capability.

The present study indicates that a Teflon® sheath surrounding a redundant electrode segment will prevent the ingrowth of fibrous tissue in a high percentage of cases. When shielded in this manner, both a loop and sinusoidal pattern of redundant electrode wire expanded well during head growth. The scant amount of fibrous tissue seen inside of the Teflon® bag in several cases did not impair expandability, presumably because it was too thin and friable to restrict electrode movement. The dense fibrous tissue encasing the free curved end of the "type C" electrode and binding it down to the surrounding tissues demonstrates the danger of leaving any redundant electrode segment unprotected. The lack of such tissue formation around the protected redundant segments attests to the efficacy of the Teflon® sheaths.

A number of considerations, however, make it difficult to come to any general conclusions based on the results of this study. The limited financial resources and space in the animal care facility made it necessary to use a small number of animals in this study. Consequently, only a small number of each type of device configuration could be tested. Also, the short time-period for follow-up was necessitated by the excessive weight achieved by

the swine. Ideally, this study would have used many more animals and would have followed them for a much longer period of time to determine the long term effects of the physiologic milieu on the expansile devices ability to prevent fibrous ingrowth.

Perhaps a more serious flaw with this study is the lack of controls incorporated into the experimental design. With more animals available, it would have been possible to leave redundant expansile segments free on the surface of the calvarium to compare the ability of the device to expand with that of the Teflon®-enclosed segments. The rationale for fastening both ends of each experimental device to the skull was that in an actual cochlear implant, the active electrode will be firmly anchored at both ends - at the round window and at the temporal squama. However, it would have been desirable to leave more than one device with one end free and unfastened to the cranium and to measure the movement of the free end along the calvarium. If the electrode changed position relative to the calvarium in devices with the redundant segments freely exposed and showed no migration relative to the underlying skull in devices with the Teflon®-enclosed redundant segments then the experiment would lend greater evidence for the need for and efficacy of a sheathed expansile device to prevent electrode displacement during head growth.

The optimal geometry of an expansile lead wire is one that favors progressive elongation without the development of opposing forces. Both a helix and a loop become tighter as they elongate with resultant increases in the force necessary for further expansion. A sinusoidal pattern, by contrast, is not inherently subject to these forces, and is therefore preferred. Also, a simple loop may be rendered non-distensible by fixation of as few as two points, while a continuously redundant pattern may remain

pliable despite multiple points of adhesion. Another advantage to the sinusoidal pattern is that it is more planar which may be important in minimizing the three-dimensional size of the device for implantation in young children. A shortcoming of the present study was that it did not adequately compare the merits of a loop or sinusoidal electrode pattern for use in a cochlear implant because two of the three sinusoidal devices were placed under a bony channel while none of the loop devices were tested under such circumstances. Another study would probably compare the ability of different redundant patterns to expand under similar circumstances and might even attempt to quantify the amount of stress/strain created by each device by use of a strain guage or other such device. Although both redundant patterns elongated sufficiently in the present study, in view of the previous discussion it would seem likely that a sinusoidal electrode pattern would be the most appropriate to be incorporated into future human devices.

An ideal expansile system would reliably exclude all fibrous tissue from the region of the redundant wire. Separation of the Teflon® bag from subcutaneous fibrous tissue by creation of a layer of bone over the device showed some promise in this study. There was no fibrous ingrowth found in the bony channel devices, nor was expansion of the electrode restricted by the bony channel. This technique has also been suggested[59] as a means to physically separate the cochlear implant and round window from the middle ear space and thus prevent bacteria from an otitis media from tracking along the length of the electrode into the cochlea, where the destructive effects of labyrinthitis could have disastrous effects on the spiral ganglion cells and the prosthesis itself.[60] This problem may be especially important in children, since 84% of children suffer at least one

episode of acute otitis media by age six[61] and multiple episodes of otitis media are common in many of them. Because of this fact, Jackler, *et al* [62] used an animal model to investigate the consequences of middle ear infection in an implanted ear. Their data has shown that intracochlear infection can occur as a result of middle ear infection in the presence of a cochlear implant when the path of the implant crosses the unsterile middle ear.

Large numbers of implanted children have been studied by House and his colleagues.[63] In their series they found that the cochlear implant did not increase the incidence or severity of otitis media in children of otitis media-prone age. Nor did these children develop meningitis or any other evidence of inner ear infection. However, the electrode devices used thus far by the House group have been of the single-channel type and only lie 6 mm into the scala tympani. This short length from the round window to the tip of the implant allows a fibrous capsule to form, which helps to seal off the cochlea from infection.[64,65] Since multi-channel electrodes extend much further into the scala, there may be no fibrous capsule formation with which to seal off the round window. Even if a fibrous capsule were able to form around the long multichannel electrode, Franz,*et al* [66] have demonstrated in cats, using horseradish peroxidase, that when such a round window membrane seal forms around the implant, a gap exists between the electrode and the membranous seal which could be a potential site for microbial invasion. The present study indicates that a strategy that consisted of preventing the spread of middle ear infection by isolating the cochlear implant from the middle ear mucosa with a bony channel would probably not impair the function of an expansile device.

Better sealing of the sheath around the electrode exit sites might improve the ability of the sheath to act as a barrier to fibrous tissue encroachment. An alternative strategy to completely prevent fibrous ingrowth would be to fill the expansile sheath with a biocompatable liquid or semi-solid material that would both lubricate the redundant wire and exclude fibrous ingrowth. Such a material is unlikely to remain unaffected by many years in a physiologic environment, but even a temporary space-occupying substance may prevent the early seepage of blood which catalyzes the formation of fibrous tissue. In addition, it might decrease the force required for the electrode lead wire to play out from the sheath, thereby decreasing the tension on the intracochlear portion of the prosthesis and the likelihood of explantation.

An interesting finding in this study is the deeply grooved bone that formed around unsheathed electrode segments. It is uncertain as to whether these grooves formed because of tension on the lead wires which caused them to cut into the underlying calvarium, or whether it was a result of growth of the skull around the relatively fixed electrodes. In either case, it is possible that this is the result of excess tension on the lead wires caused by friction at the exit points of the sheaths. Such tension on implant leads in a human device could have dire consequences if it resulted in deep grooves being cut into the structures within the temporal bone or breakage of the electrode at the point of fixation to the cochlea or temporal bone squama. Further study of the forces of extraction of the electrodes from the protective sheaths is necessary to resolve some of these issues.

Despite its limitations, this study indicates that it may be possible to accommodate for head growth in pediatric cochlear implantation by enclosing redundant electrode lead wire segments in a protective Teflon®

sheath to prevent fibrous tissue ingrowth. Such an expansile device, incorporated into future cochlear implants, may make it increasingly possible to implant young children with sophisticated multichannel cochlear prostheses while significantly decreasing the likelihood of gross movement or explantation. The effect would be to improve the long-term functional capability of the prosthesis, thus maximizing the clinical benefit to the patient.

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